

REMARKS

By the foregoing amendment, claims 1, 15, 29 and 53 have been amended to further clarify Applicants' invention. No new matter has been added.

Rejection under 35 U.S.C. § 102

Claims 1-12, 15-26, 52 and 53 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Stockmann et al. (DE 4344463A1). Applicants respectfully traverse this rejection.

The present invention defines a multi-phase preparation and a pharmaceutical kit comprising a predetermined ordered daily sequence of individual daily dosages. The claims further define the ordered sequence of the daily dosage units, which provides daily dosage units of progesterone antagonist followed by the separate administration of daily dosage units of a gestagen. The amount of progesterone antagonist administered is effective to inhibit ovulation.

Stockmann et al. is drawn to methods and compositions using a progesterone antagonist in a non-ovulation inhibitory dose, rather than an ovulation-inhibitory dose as instantly claimed. As discussed in the previous response, a single dose of a given amount of a progesterone antagonist can have different effects if administered daily or weekly. Stockmann et al. does not disclose ovulation inhibitory doses as claimed, but rather the opposite effect only. One cannot use the disclosure of Stockmann et al. to arrive at the presently claimed invention.

Further, the cited reference does not describe an ovulation inhibiting dose of a progesterone antagonist in the context of a multiphase preparation comprising a first phase using a progesterone antagonist and a second phase using a gestagen. In order for a reference to be anticipatory, it must disclose every element of a claim. That is clearly not the case here.

The action noted that a recitation of the manner of administration of a pharmaceutical kit or composition is not considered a limitation of a pharmaceutical kit or composition itself, and will not further limit claims drawn to a composition or product, such as a pharmaceutical kit. This can be true. However, it is irrelevant here. This is not a case of the prior art disclosing the same doses and regimen for a given drug or set of drugs. Stockmann's doses and regimen necessarily differ because the effect to be achieved using the same drugs is the opposite.

As stated above, the present invention defines a pharmaceutical kit comprising a predetermined ordered daily sequence of individual daily dosages. The claims further define the ordered sequence of the daily dosage units. The cited reference does not describe such a multi-phase preparation or kit.

Therefore, the rejection under 35 U.S.C. § 102(a) should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 1-12, 15-26, 29-32, 48 and 51-53 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stockemann et al. (DE 4344463A1). Applicants respectfully traverse this rejection.

Stockemann et al. also does not render the instant claims obvious. As stated above, this reference does not teach ovulation inhibitory doses or doses that induce amenorrhea. This is not a mere difference in intended use but rather involves different doses/regimen details resulting in an effect opposite to that of this reference.

Further, there is no teaching or suggestion in the cited reference that would motivate a worker to select an ovulation inhibiting dose for a progestagen antagonist and use that dose in the "combination" disclosed in the cited reference. In addition, there is no suggestion or teaching in the cited reference to motivate a skilled worker to provide the non-obvious combination preparation or the claimed preparation combination in a kit as claimed (i.e., a predetermined ordered daily sequence of individual daily dosages). Absent such motivation in either case, with the requisite expectation of success, the cited reference does not render the claimed invention obvious.

Therefore, the rejection under 35 U.S.C. § 103(a) should be withdrawn.

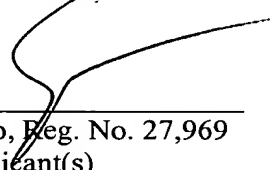
In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney or agent concerning such questions so that prosecution of this application may be expedited.

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The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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